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18M1/1112

EXAMINER	
ALLEN, M	
ART UNIT	PAPER NUMBER
1818	3/

DATE MAILED:

11/12/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

2- APPLICANT'S COPY

Office Action SummaryApplication No.
08/583,491Applicant(s)
LeeExaminer
Marianne P. AllenGroup Art Unit
1818☒ Responsive to communication(s) filed on Jan 5, 1996☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 3, 11-15, 22, and 23 is/are pending in the application.Of the above, claim(s) 23 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 3, 11-15, and 22 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim 2 has been cancelled. Claims 22-23 have been newly added. Claims 3, 11-15, and 22-23 are under consideration by the Examiner.

5 Claim 23 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. The restriction requirement was made final in Paper No. 6.

10 Claims 3, 11-15, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15 The specification fails to enable how to use the GDF-1 protein in the manner set forth in the specification. Claims 3 and 22 are drawn to DNA segments encoding mammalian GDF-1 protein. Claims 11-14 are directed to vectors and transformed host cells and claim 15 is directed to a method of producing the protein. Biological
20 properties are alleged based upon the similarity of the GDF-1 amino acid sequence to the TGF- β family. However, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties. (See specification

pages 10-11.) The similarities between GDF-1 and the TGF- β family members range from 26-52% on the amino acid level and these proteins are not deemed to be predictive of the biological properties possessed by GDF-1. The biological activities of the TGF- β family are diverse and it could not be predicted which activity GDF-1 would have, if any. As such, the specification does not enable using the GDF-1 protein or DNA sequence as disclosed in the specification. For example, there is no evidence of any disease state that can be treated with this protein nor any tumors, genetic diseases, or developmental anomalies that applicant has associated with this gene or protein.

With respect to claim 15, expression of GDF-1 is described on page 6 in the description of figure 9; however, insufficient details are presented to determine what was performed. It does not appear that the protein was isolated as set forth in the claimed method. There does not appear to be a further discussion of figure 9 and the recombinant production of GDF-1 in the specification. It is deemed to be unpredictable whether the protein could be successfully produced recombinantly in the absence of a clear description of its production which the specification lacks. As

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such, the method of claim 15 is not sufficiently described nor enabled.

It would constitute undue experimentation to determine how to use the claimed invention in the manner set forth in the specification.

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Claims 3, 11-15, and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 22 recites "sequence of Figure 2 or Figure 3." However, there is no figure 3. There are Figures 3A and 3C which contain amino acid sequences. It is unclear what is intended.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The most convenient FAX telephone number for this examiner is (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.